TFW

PE 45AS:gp/gsh/dnr 10/24/05 5673-66690-01 379602.doc cp14/01-us6

**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re application of: Swain et al.

**Application No.** 10/647,071

Filed: August 22, 2003 Confirmation No. 9609

For: HAPTEN-CARRIER CONJUGATES FOR

USE IN DRUG-ABUSE THERAPY AND METHODS FOR PREPARATION OF

**SAME** 

Examiner: Unassigned

Art Unit: 1641

Attorney Reference No. 5673-66690-01

COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

#### **CERTIFICATE OF MAILING**

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s)

Date Mailed October 25, 2005

### INFORMATION DISCLOSURE STATEMENT FOR CONTINUING APPLICATIONS

Listed on the accompanying form PTO-1449 are several English-language and/or non-English-language documents. Applicants respectfully request that such documents be listed as references cited on the issued patent.

The present application relies upon U.S. Patent Application No. 10/115,580 filed April 1, 2002, which is a continuation of U.S. Patent Application No. 09/882,803 filed June 14, 2001, which is a continuation of U.S. Patent Application No. 09/257,821, filed February 25, 1999, which is a continuation of U.S. Patent Application No. 08/720,487, filed September 30, 1996, which is a continuation-in-part of U.S. Patent Application No. 08/563,673, filed November 28, 1995, which is a continuation-in-part of U.S. Patent Application No. 08/414,971, filed March 31, 1995, for an earlier filing date under 35 U.S.C. § 120. Furthermore, documents listed on the accompanying form PTO-1449 were disclosed to or cited by the Patent Office in the earlier U.S. applications.

Copies of United States patents and United States published patent applications do not have to be provided to the Patent Office (37 C.F.R. 1.98(a)(2)(ii)). Copies of unpublished U.S.

applications do not have to be provided, as long as the application is available on PAIR, as this requirement of 37 C.F.R. § 1.98(a)(2)(iii) has been waived by the United States Patent and

Trademark Office pursuant to the Official Gazette Notice on October 19, 2004 (1287 OG 163).

Applicants will provide copies of such patents or applications upon request.

Copies of the documents listed on the accompanying form PTO-1449 that were cited by applicants or cited by the Patent Office in an earlier application need not be sent to the Patent Office pursuant to 37 C.F.R. § 1.98. However, applicants will furnish the Patent Office with such copies upon request.

Please charge any additional fees that may be required in connection with filing this Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 02-4550. A duplicate copy of this sheet is enclosed.

The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600 121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 595-5300

Facsimile: (503) 595-5301

cc: Docketing

Susan-Alpert Siegel, Ph.D. Registration No. 43,121

OCT 2.8 1005
EFORMATION DISCLOSURE STATEMENT
BY APPLICANT

Attorney Docket Number	5673-66690-01
Application Number	10/647,071
Filing Date	August 22, 2003
First Named Inventor	Philip A. Swain
Art Unit	1641
Examiner Name	To be assigned

### **U.S. PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
<del>"</del>		3,888,886	10 June 1975	Young et al.
		4,045,420	30 Aug 1977	Soffer et al.
<del> ç</del>		4,123,431	31 Oct 1978	Soffer et al.
		4,129,237	12 Dec 1978	Grinder
		4,197,237	08 Apr 1980	Leute et al.
		4,235,864	25 Nov 1980	Kaul et al.
		4,375,414	01 Mar 1983	Strahilevitz
		4,376,825	15 Mar 1983	Rubenstein et al.
		4,620,977	04 Nov 1986	Strahilevitz
		4,666,837	19 May 1987	Harford et al.
		4,791,067	13 Dec 1988	Sheiman et al.
• • • • • • • • • • • • • • • • • • • •		4,813,924	21 Mar 1989	Strahilevitz
		4,834,973	30 May 1989	Strahilevitz
		5,019,384	28 May 1991	Gefter et al.
		5,037,645	06 Aug 1991	Strahilevitz
		5,229,490	20 July 1993	Tam

EXAMINER	DATE
SIGNATURE:	CONSIDERED:

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Attorney Docket Number	5673-66690-01
Application Number	10/647,071
Filing Date	August 22, 2003
First Named Inventor	Philip A. Swain
Art Unit	1641
Examiner Name	To be assigned

### **U.S. PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		5,256,409	26 Oct 1993	Blincko
		5,268,276	07 Dec 1993	Holmgren et al.
<b>.</b>		5,283,066	01 Feb 1994	Liu et al.
		5,876,727	02 Mar 1999	Swain et al
<u> </u>		6,210,677	03 Apr 2001	Bohannon
			· ·	

### **FOREIGN PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		Europe	EP 0 311 383	Apr 1989	UBE INDUSTRIES
		Europe	EP 0 363 041	Apr 1990	UBE INDUSTRIES
		Europe	EP 0 613 899 A2	Sep 1994	MATSUSHITA ELECTRIC IND CO LTD
		Germany	DE2202441	Mar1973	HOFFMANN LA ROCHE
		Germany	DE2548196	Apr 1977	HOFFMANN LA ROCHE
		Soviet Union	792869	Mar 1982	NII BIOLOG ISPYTANIYAM KHIM SO

EXAMINER	DATE
SIGNATURE:	CONSIDERED:

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Attorney Docket Number	5673-66690-01
Application Number	10/647,071
Filing Date	August 22, 2003
First Named Inventor	Philip A. Swain
Art Unit	1641
Examiner Name	To be assigned

### FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee		
		Soviet Union	1123704A	Nov 1984	NII BIOLOG ISPYTANIYAM KHIM SO		
		PCT	WO 92/03163	Mar 1992	CERNY ERICH H		
•		PCT	WO 93/12111	June 1993	BIOSITE DIAGNOSTICS INC		
-		PCT	WO 93/23076	Nov 1993	UNIV JOHNS HOPKINS		
,		PCT	WO 94/27576	Dec 1994	DANBIOSYST; ILLUM LISBETH		
		PCT	WO 95/07922	Mar 1995	SMITHKLINE BEECHAM CORP; LEE JOHN C		
		PCT	WO 95/27786	Oct 1995	IMMULOGIC PHARMA CORP		
		PCT	WO 96/30049	Mar 1996	IMMULOGIC PHARMA CORP		
Examiner's Initials*	Cite No. (optional)		<b>O</b> 1	THER DOCUMENTS	S		
			in Humans," <i>Journ</i> e	Benzoylecgonine Disp al of Analytical Toxico	position after Cocaine plogy Vol. 15, pp. 17-20,		
		. •	al., "A Potential Vaccine for Cocaine Abuse Prophylaxis," urmacology 23:173-179, 1992				
		Beckstead et al. Complex of O <sup>6</sup> -	, "Fourier Transford Acetylmorphine,"	m-Infrared (FT-IR) Ch I. Forensic Sci., Vol. 3	aracterization of Ethyl Acetate 3(1):223-229, January 1988		
		Complex of O <sup>6</sup> -	Acetylmorphine," (	Chem. Abs. 108:14483			
		Berkower, "Syr Institute 1009-1		pe Peptides Used for D	Desensitization," Paul-Ehrlick-		
		Berkowitz, "Ev 1292, 1972	idence for Active In	nmunity to Morphine	in Mice," Science 178:1290-		

EXAMINER	DATE
SIGNATURE:	CONSIDERED:

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

	Attorney Docket Number	5673-66690-01
	Application Number	10/647,071
INFORMATION DISCLOSURE STATEMENT	Filing Date	August 22, 2003
BY APPLICANT	First Named Inventor	Philip A. Swain
	Art Unit	1641
•	Examiner Name	To be assigned
Berkowitz, "Influence of Active and		sposition of
Dihydromorphine-H <sup>3</sup> ," Life Sciences		
Bonese et al., "Changes in Heroin Se		us Monkey after
Morphine Immunisation," <i>Nature</i> 25 Carroll et al., "Effects of Buprenorph		of Cossins and a
Nondrug Reinforcer in Rats," Psycho		
Carroll et al., "Chemical Approaches		
1:11-17, 1994		1 100000, 1 1100110110110
Castro et al., "Nicotine Antibody Pro		
Different Animal Species," Biochem	ical and Biophysical Researc	ch Communications Vol.
67, No. 2, pp. 583-589, 1975	C	6-141 C A - 411 - 31
Castro et al., "Nicotine Antibodies: Produced against Two Nicotine Con		
Castro et al., "Characterization of Ar		
178, 1985	induction in the child, Broom	omical III control 1.175
Castro et.al., "Nicotine Enzyme Imm	nunoassay," Research Comm	unications in Chemical
Pathology and Pharmacology 51:39:		
Castro et al., "Nicotine Antibodies: (		
Produced against Two Nicotine Cong Castro et al., "Characterization of Ar		
Castro et al., Characterization of Ar	illoudies to Nicotine, Chem	. Abs. 105:215004, 1998
Chuong et al., "Study on Anti-Aspiri		
with Various Aspirin-Protein Conjug	gates," Annales Pharmaceuti	ques Françaises 35(7-
8):257-264, 1977 (Translation)	ah Erramonta ta Altar the Dh	
Colburn, "Specific Antibodies and F Reverse the Pharmacologic/Toxicologic		
262, 1980	ogic Directs of Drugs, Drug	Memou Nev. 11.225-
Curreru et al., "Suppression of Cocai	ine-Induced Locomotion by	Immunization with a
Novel Cocaine Conjugate," Society of	of Neuroscience 754.4, 1993	(Abstract)
Decato et al., "Immunologic Studies		
Cocaine Metabolites and Their Use f	for Drug Detection," Journal	of Immunological
Methods 18:201-213, 1977 Gallacher, "A Potential Vaccine for the second	Cocaine Ahuse Dronhulovica	"Immunonharm 27.70
81, 1994	Cocame Abuse Flophylaxis?	1mmunopnarm. 27:19-
1 (2.) *// '		

EXAMINER DATE CONSIDERED:
---------------------------

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

		Attorney Docket Number	5673-66690-01	
		Application Number	10/647,071	
INFORMATION DISCLOSURE STATEMENT		Filing Date	August 22, 2003	
	BY APPLICANT	First Named Inventor	Philip A. Swain	
		Art Unit	1641	
		Examiner Name	To be assigned	
	Harless et al., "Abstract: Active Im-	munization Prevents Analges	sic and Reinforcing	
-	Effects of Cocaine," Twenty-fourth	Effects of Cocaine," Twenty-fourth Annual Western Psychology Conference, April 1995		
	Herndon et al., "Attenuation of Morphine Analgesia by Serum from Morphine-Treated Rabbits," Life Sciences 17:151-158, 1975			
	Holmgren et al., "Strategies for the		ses at Mucosal Surfaces	
	Making Use of Cholera Toxin B Subunit as		, and Adjuvant," Am. J.	
	Trop. Med. Hyg. pp. 42-54, 1994		· · · · · · · · · · · · · · · · · · ·	
.	Inaba, "Cocaine: Pharmacokinetics and Biotransformation in Man," SFBS Symposium on			
	Frontiers in Cocaine Research, Quebec, Canada, pp. 1154-1157, June 15, 1988			
.	Inaba, "Cocaine: pharmacokinetics and biotransformation in man," Can. J. Physiol. Pharmacol. 67:1154-1157, 1989			
	Jatlow, "Cocaine: Analysis, Pharmacokinetics, and Metabolic Disposition," <i>The Yale</i>			
	Journal of Biology and Medicine 61:105-113, 1988			
	Jindal et al., "Mass spectrometric studies of cocaine disposition in animals and humans			
	using stable isotope-labeled analogues," J. Pharm. Sciences 78(12):1009-10014, 1989			
	, ,	Jones-Witters et al., Drugs and Society - A Biological Perspective, Wadsworth Health		
	Services Division, Wadsworth, Inc., Belmont, CA, 94002, pp. 142-147, 1983			
	Kantak et al., "Acute and Multiple Injection Effects of Magnesium on Responding			
	Maintained by Cocaine, Extinction from Cocaine, Glucose + Saccharin, and Food,"  Pharm. Biochem. and Behavior, 41:415-423, 1992			
	Killian et al., "Effects of Passive Immunization Against Morphine on Heroin Self-			
	Administration," Pharmacol. Biochem. Behavior 9:347-352, 1978			
	Kovalev et al., "Diminishment of the Effects of Morphine in Rats Immunized with a			
	Morphine-Protein Conjugated Antigen," Khim. Pharm. (USSR) pp. 615-618, 1979			
	Kovalev et al., "Effect of the Active Immunization of Rats Using a Conjugate of			
	Morphine with Bovine Serum Albumin (M-BSA) on the Self-Consumption of Morphine,"			
	Khim. Pharm. (USSR) pp. 200-204,	·		
	Landry et al., "Antibody-Catalyzed Degradation of Cocaine," Science 259:1899-1901, March 26, 1993			
	Lomax et al., "Immunological Blockade of the Analgesic Effect of Morphine in the Rat," Proc. West. Pharmacol. Soc. 16:252-256, 1973		of Morphine in the Rat,"	
	Manganaro, "Oral Immunization: Turning Fantasy into Reality," Int. Arch. Immunol. 103:223-233, 1994		Int. Arch. Immunol.	

	EXAMINER SIGNATURE:	DATE CONSIDERED:
--	------------------------	---------------------

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

	Attorney Docket Number	5673-66690-01	
	Application Number	10/647,071	
INFORMATION DISCLOSURE STATEMENT	Filing Date	August 22, 2003	
BY APPLICANT	First Named Inventor	Philip A. Swain	
	Art Unit	1641	
•	Examiner Name	To be assigned	
Matsushita et al., "Conjugate of Boy			
Biophysical Research Communications Vol. 57, No. 4, pp 1006-1010, 1974			
	McKenzie et al., "Cholera Toxin B Subunit as a Carrier Protein to Stimulate a Mucosal		
	Immune Response," The Journal of Immunology 133(4):1818-1824, October 1984		
	Miller et al., "Attenuation of Morphine Analgesia by Immunological Manipulations," Proc. West Pharmacol. Soc. 17:69-72, 1974		
	Proc. West Pharmacol. Soc. 17:69-72, 1974  Pentel et al., "Redistribution of Tricyclic Antidepressants in Rats Using a Drug-Speci		
Monoclonal Antibody: Dose-Response Relationship," Drug Meth. & Disp. 19:24-28,			
Schmidt et al., "Immunological Protection against Digoxin Toxicity," The Journal of			
Clinical Investigation 50:866-871, 1971			
	Slos, "Recombinant Cholera Toxin B Subunit in Escherichia coli: High-Level Secretion,		
	Purification, and Characterization," Protein Expression and Purification 5:518-526, 1994		
Spector et al., "Morphine: Radioimi	Spector et al., "Morphine: Radioimmunoassay," Science 168:1347-1348, 1970		
Spector, "Quantitative Determination	Spector, "Quantitative Determination of Morphine in Serum by Radioimmunoassay," The		
	Journal of Pharmacology and Experimental Therapeutics 178:253-258, 1971		
	Spector et al., "Antibodies to Morphine, Barbiturates, and Serotonin," Pharmacological		
	Reviews Vol. 25, No. 2 pp. 281-291, 1973		
Spector, "Antibodies as Pharmacolo 2428, 1976	Spector, "Antibodies as Pharmacological Agents," <i>Biochemical Pharmacology</i> 25:2427-2428, 1976		
	Stok et al., "Conversion of Orally Induced Suppression of the Mucosal Immune Response to Ovalbumin into Stimulation by Conjugating Ovalbumin to Cholera Toxin or its B		
Subunit," Vaccine Vol. 12, No. 6, pp	Subunit," Vaccine Vol. 12, No. 6, pp 521-526, 1994		
Van Vunakis et al., "Specificities of antibodies to morphine," The Journal of			
Pharmacology and Experimental Therapeutics 180:514-521, 1972  Wainer et al. "Marphine 2 Susainal Pavine Sarum Albumine An Immune genia Honton			
	Wainer et al., "Morphine-3-Succinyl-Bovine Serum Albumin: An Immunogenic Hapten- Protein Conjugate," <i>Science</i> 176:1143-1145, 1972		
	Wainer et al., "The Structure of Morphine Monohemisuccinate," Science 178:647-648,		
November 10, 1972	r,	22.0	
February 23, 1973	Wainer et al., "In Vitro Morphine Antagonism by Antibodies," Nature 241:537-538,		
Wainer et al., "A Measurement of th BSA by Competitive Inhibition of <sup>14</sup> Vol. 110, No. 3, pp 667-673, March	C-Morphine Binding," The J	to Morphine-6-Succinyl- Journal of Immunology	

EXAMINER DATE SIGNATURE: CONSIDERED:
--------------------------------------

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

		Attorney Docket Number	5673-66690-01	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/647,071	
		Filing Date	August 22, 2003	
		First Named Inventor	Philip A. Swain	
		Art Unit	1641	
•		Examiner Name	To be assigned	
· .	and Biobehavioral Reviews, Vol. 18 Wu et al., "Comparison of Systemic	Witkin, "Pharmacotherapy of Cocaine Abuse: Preclinical Development," Neuroscience and Biobehavioral Reviews, Vol. 18, No. 1, pp 121-142, 1994  Wu et al., "Comparison of Systemic and Mucosal Priming for Mucosal Immune Responses to a Bacterial Protein Antigen Given with or Coupled to Cholera Toxin (CT) B		
	Subunit, and Effects of Pre-Existing Anti-CT Immunity," <i>Vaccine</i> Vol. 12, No. 3, pp. 215-222, 1994			
	Zimmerman et al., "Immunological Suppression of Morphine Induced Analgesia and			
	Pituitary-Adrenal Activation in the Rat and Respiratory Depression in the Rabbit," <i>Proc. West. Pharmacol. Soc.</i> Vol, 19, pp. 260-265, 1976			

EXAMINER	DATE
SIGNATURE:	CONSIDERED:
	00110221021

<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.